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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,050

09/19/2006

Tim W. Christensen

NOVA-001

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EXAMINER

SNYDER, STUART

ART UNIT

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1648

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,050	<b>Applicant(s)</b> CHRISTENSEN, TIM W.	
	<b>Examiner</b> STUART W. SNYDER	<b>Art Unit</b> 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election without traverse of Group II, claims 9-16 in the reply filed on 2/4/2008 is acknowledged.

In a telephonic interview between Mr. John L. Welsh, Esq. and the Examiner on 5/13/2008, the species election requirement was clarified; Mr. Welsh elected peracetic acid as the chemical additive. All claims of the group read on the elected species.

Claims 1-8 and 17-20 are provisionally withdrawn from examination.

***Claim Rejections - 35 USC § 112, 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 9-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some microorganisms, does not reasonably provide enablement for any organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The claims are drawn to a method of "making immunogenic preparation[s] comprising contacting whole organisms with a fluid comprised of carbon dioxide at or near its supercritical pressure and temperature conditions...". As written, the claim reads on organisms other than

microorganisms such as mice, horses or elephants. Furthermore, in the case of certain fungi such as *Armillaria ostoyae*, it is well-known that the size of one organism may span over 1500 acres. Although the method would most probably be effective in reducing a population of relatively large organisms by a factor of at least one million, the size of a vessel required to "inactivate" one million elephants or mycelia of the aforementioned fungi would be so large as to preclude its construction.

***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 contains the phrase "said whole organisms are inactivated by at least a factor of  $10^6$ ". The phrase may be reasonably construed to mean that each individual organism has diminished activity by a factor of  $10^6$ ; such is the case, for example, when external conditions result in recombinant bacteria down regulation of exogenous gene production. Certain aspects of organisms are binary--whole organisms at physiological conditions are either individually capable of replication or incapable of replication; whole organisms are either individually capable of infection or incapable of infection of susceptible hosts. Other aspects of organisms are manifest along a spectrum—enzyme activity may be up or down regulated depending on the

physiological state of the organism, environmental conditions may result in coordinated or directed mobilization as observed when certain motile bacteria are placed in a nutritional gradient. Thus, it is unclear from the language of the claim whether the method is intended to encompass both binary and incremental aspects of individual organism of a group or the method is intended to encompass the overall activity of a group of organisms. Applicants may wish to amend the claim language, as supported by the disclosure and more consistent with Applicants' intended meaning to recite a method for reducing the infectivity of the vaccine preparation to read, for example, "the infectivity and/or pathogenicity of said whole organisms is reduced by a factor of at least  $10^6$ ".

4. The phrase "from 0.001% to 2.0%" is indefinite and unclear. It is well known in the chemical arts that description of concentration in percentage terms require one of the following modifiers: w/w, w/v or v/v; the abbreviations refer to weight-to-weight, weight-to-volume and volume-to-volume descriptions which are necessary when additives have a different specific gravity than 1.0.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 9 and 16 rejected under 35 U.S.C. 102(b) as being anticipated by Lin, et al. The claims are drawn to a method of making an immunogenic preparation comprising contacting whole organisms with a fluid comprised of carbon dioxide at or near its supercritical pressure and temperature (superfluid) such that the whole organisms are inactivated (infectivity and replicative capacity) are reduced by at least a factor of  $10^6$ . Claim 16 adds the additional step of growing the organism to at least  $10^6$  prior to inactivation.

Lin teaches a method of inactivating yeast cells (an inherently immunogenic preparation) by a factor of greater than  $10^7$  comprising contacting a yeast culture with superfluid carbon dioxide for about 30 minutes. Thus, all of the limitations of claims 9 and 16 are taught by Lin, et al. which clearly anticipates the instantly claimed invention.

6. Claims 9, 10, and 16 rejected under 35 U.S.C. 102(e) as being anticipated by Castor, et al. (U.S. Patent 7033813, issued April 25, 2006). The claims are drawn to a method of making an immunogenic preparation as described above (see section 5) Claim 10 adds the presence of a "chemical additive" to the superfluid. Castor, et al. teaches a method of preparing a potential vaccine and actual immunogen of HIV that inactivates HIV by a factor of at least 10 per treatment of HIV with superfluid carbon dioxide (see Table 2). Castor, et al. further teach that that the process can be repeated to achieve the desired level of inactivation (in the case of a vaccine for use in humans, fully inactive), "the level of inactivation

can be increased to more than 6 logs by adding a second stage or pass to the process" while referring to one method using nitrous oxide/carbon dioxide superfluids (see column 7, line 56 and following as well as Figure 4 that incorporates 5 stages into an apparatus for performing the method effectively achieving 5 passes). Furthermore, other chemical additives can be included in the superfluid composition (see column 8, lines 21 and following). Finally, while stipulating that the virion infectivity had an upper limit of detection of  $\sim 4 \times 10^4$  TCID<sub>50</sub>/ml, it is clear from the described exemplary experiments and the general knowledge in the art of HIV virology, that at least  $10^6$  virions were produced for each production run of the starting virus. Thus, all of the limitations of the claims are taught by Castor, et al. which properly anticipates the claimed invention of the claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lin, et al., in view of Kamihira, et al. The limitations of the base claims are described above. Claims 11-13 limit the nature of the additives and include the addition of acetic acid to the superfluid carbon dioxide composition.

Kamihira, et al. teaches sterilization methods of certain food stuffs using superfluid carbon dioxide and includes the addition of acetic acid at 0.5% (w/w) in the sterilization composition to achieve an approximate reduction in viability of *A. niger* cells of  $\sim 10^7$ . As stated throughout the method, a prime concern in these sterilization methods are the maintenance of the quality of the food stuffs being sterilized, especially a precursor ingredient of sake; demonstration of the minimal change to enzyme function and activity by the authors (see Table IV) further bolsters the concept of maintaining protein structure while reducing pathogen load--the same goals as stated by Lin, et al. in preparation of potential vaccines. Furthermore, it is clear from the data (see Table III) that addition of acetic acid to the sterilization composition increased the efficacy of the method.

It would have been obvious to one of ordinary skill in the art to modify the methods taught by Lin, et al. by adding acetic acid or other chemicals, as taught by Kamihira, et al. in order to arrive at the instantly claimed invention. One would have been motivated to do so given the suggestion by Kamihira, et al. that protein structure and function, and hence immunogenicity, would be retained and the efficacy of the sterilization method increased by the addition of acetic acid.

There would have been a reasonable expectation of success given the knowledge that a variety of microbes are sterilized as taught by Kamihira, et al. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

***Allowable Subject Matter***



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8. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
9. No claims are allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to STUART W. SNYDER whose telephone number is (571)272-9945. The examiner can normally be reached on 9:00 AM-5:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce R. Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.  
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./  
Primary Examiner, Art Unit 1648

Stuart W Snyder  
Examiner  
Art Unit 1648

SWS